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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/063,578	05/03/2002	Dan L. Eaton	P3230RIC001-168	2392

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EXAMINER

HUNNICUTT, RACHEL KAPUST

ART UNIT

PAPER NUMBER

1647

DATE MAILED: 08/24/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/063,578	EATON ET AL.	
	Examiner	Art Unit	
	Rachel K. Hunnicutt	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 September 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-6 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-6 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 03 May 2002 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>0902</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Priority

According to the priority statement of September 9, 2002, the claimed subject matter defined in the instant application is supported by parent application serial nos. 10/006867, PCT/US00/23328, 09/380137, PCT/US99/12252, and 60/090246. Based on the information given by Applicant and an inspection of the patent applications, the examiner has concluded that the subject matter defined in this application is not supported by the disclosures of 09/380137, PCT/US99/12252, and 60/099763 because the priority documents are not enabling for the claimed antibody which binds to the PRO 1158 polypeptide. The current application is a continuation of 10/006867, which is a continuation of PCT/US00/23328 filed August 24, 2000, all of which have the same specification and disclose the same subject matter. Accordingly, the subject matter defined in claims 1-6 has an effective filing date of August 24, 2000.

Should the Applicant disagree with the examiner's factual determination above, it is incumbent upon the Applicant to provide the serial number and specific page number(s) of any parent application filed prior to August 24, 2000 that specifically supports the particularly claim limitation for each and every claim limitation in all the pending claims which Applicant considers to have been in possession of and fully enabled prior to August 24, 2000.

Specification

The use of the trademarks KLENTAQ™ (p. 117), QIAQUICK™ (p. 119), SUPERFECT™ (p. 129), FUGENE™ (p. 129), and BACULOGOLD™ (p. 131) have been noted in this application. They should be capitalized wherever they appear and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

Art Unit: 1647

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-6 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility. Claims 1-6 are directed to antibodies which bind to polypeptides comprising SEQ ID NO: 68. The claimed antibodies are not supported by either a specific and substantial asserted utility or a well-established utility.

A specific and substantial utility is one that is particular to the subject matter claimed and that identifies a “real world” use for the claimed invention. See *Brenner v. Manson*, 148

U.S.P.Q. 689 (1966):

The basic quid pro quo contemplated by the Constitution and the Congress for granting a patent monopoly is the benefit derived by the public from an invention with substantial utility. . . . [u]nless and until a process is refined and developed to this point-where specific benefit exists in currently available form-there is insufficient justification for permitting an applicant to engross what may prove to be a broad field.

The antibodies of the current invention bind to polypeptides comprising SEQ ID NO: 68. However, there is no utility for a polypeptide comprising SEQ ID NO: 68. Uses such as assaying for binding partners (p. 89), using polypeptides as molecular weight markers (p. 92), and screening for agonists and antagonists of PRO 1158 (p. 95) are useful only in research to determine the function of the encoded protein itself. There is no “specific benefit in currently available form” to be derived from such studies.

Applicants also assert that the antibodies may be modified so that they are effective in the treatment of cancer and HIV infection (p. 108). Applicants further assert the antibodies may be used in pharmaceutical compositions for the treatment of various disorders (p. 110). However, the specification does not disclose any diseases or conditions known to be associated with the encoded PRO 1158 polypeptide. Further research would be required to identify a disease in which the encoded polypeptide is involved. See *Brenner v. Manson*, noting that “a patent is not a hunting license. It is not a reward for the search, but compensation for its successful

Art Unit: 1647

conclusion.” A patent is therefore not a license to experiment. Further research would be required to determine how and if PRO 1158 is involved in any disease.

The invention also lacks a well-established utility. A well-established utility is a specific, substantial, and credible utility that is well known, immediately apparent, or implied by the specification’s disclosure of the properties of a material. The specification fails to assert any activity for the encoded PRO 1158 polypeptide. Applicants have not asserted that PRO 1158 is a member of any protein family nor have Applicants asserted that PRO 1158 is homologous to any known proteins. Thus, there is no well-established utility for PRO 1158.

Claims 1-6 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 6 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 6 is drawn to an antibody that specifically binds to a polypeptide having the amino acid sequence of SEQ ID NO: 68 (PRO 1158). The term “specifically binds” is a relative term which renders the claim indefinite. The term is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one skilled in the art would not be reasonably apprised of the scope of the invention. It is unclear what amount of binding would be considered to be “specific”. One skilled in the art would not know what the metes and bounds of specific binding are.

Art Unit: 1647

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-6 are rejected under 35 U.S.C. 103(a) as being unpatentable over either NCBI Accession No. BE531149 or AI889075 (NCBI Accession No. BE531149, Strausberg, created August 7, 2000, updated August 9, 2000; NCBI Accession No. AI889075, Strausberg created July 26, 1999, updated September 1, 1999) in view of U.S. Patent No. 6,262,234. Claims 1-6 are drawn to antibodies that bind to the polypeptide consisting of SEQ ID NO: 68. The antibodies can be monoclonal, humanized or labeled. They may also be fragments of antibodies. NCBI BE531149 teaches a nucleic acid sequence which encodes a polypeptide 100% identical to SEQ ID NO: 68 (see attached sequence alignment). NCBI Accession No. AI 889075 teaches a nucleic acid sequence which encodes a polypeptide 92% identical to SEQ ID NO: 68 (see

Art Unit: 1647

attached sequence alignment). However, neither accession no. teaches antibodies that bind to the encoded polypeptides.

The '234 patent teaches monoclonal antibodies, antigen-binding fragments, humanized antibodies, and labeled antibodies for use in characterizing novel polypeptides (see column 18). It would have been obvious to a person of ordinary skill in the art to make such antibodies because it is a commonly employed laboratory technique. One of ordinary skill in the art would have been motivated to do so because such antibodies are used for further characterization of novel polypeptides. Therefore, the invention taken as a whole is *prima facie* obvious over the prior art.

Conclusion


NO CLAIMS ARE ALLOWED.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rachel K. Hunnicutt whose telephone number is (571) 272-0886. The examiner can normally be reached on Mon-Fri 8:30 am - 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback can be reached on (571) 272-0961. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

RKH
8/19/04


JANET ANDRES
PRIMARY EXAMINER